IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION	**Case No. 2:18-md-2846**
	CHIEF JUDGE EDMUND A. SARGUS **Magistrate Judge Kimberly A. Jolson**

This document relates to:

BETTY SACKETT and
RICHARD SACKETT

Plaintiffs file this Complaint pursuant to Case Management Order No. 1 and are to be bound by the rights, protections, and privileges and obligations of this Order.

Plaintiffs, by and through their undersigned counsel, bring this Complaint for damages against Defendants and in support thereof state the following:

1. This is a device tort action brought on behalf of the above named Plaintiffs arising out of the failure of the Defendants' hernia mesh product. As a result, Plaintiff Betty Sackett suffered permanent injuries and significant pain and suffering, emotional distress, medical expenses, and diminished quality of life. The Plaintiffs respectfully seek all damages to which they may be legally entitled.

STATEMENT OF PARTIES

2. Plaintiffs are, and were, at all relevant times, citizens and residents of Iowa and the United States.

3. C.R. Bard, Inc. ("Bard") is incorporated and based in New Jersey. Bard is a multinational marketer, promoter, seller, producer, manufacturer, and developer of medical devices. Bard controls the largest market share of the hernia mesh market. Bard is the parent

company of Davol.

4. Davol, Inc. ("Davol") is incorporated in Delaware and has its principal place of business in Rhode Island. Davol is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including hernia meshes composed of polypropylene, and polyglycolic acid (PGA) fibers coated with Sepra Technology, a bioresorbable, chemically modified sodium hyalurnate, carboxymethylcellulose, and polyethylene glycol based hydrogel (hereinafter "ST Bard Mesh" or "product").

5. Defendants are individually, jointly and severally liable to Plaintiffs for damages suffered by Plaintiffs arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its defective ST Bard Mesh at issue in the instant suit, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

6. Defendants are vicariously liable for the acts and/or omissions of their employees and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

VENUE AND JURISDICTION

7. This action is being filed in this Court in accordance with Case Management Order No. 1 in the above-captioned litigation as provided in 28 U.S.C. § 1407. Venue is otherwise appropriate in the United States District Court for the Southern District of Iowa, which has diversity subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332.

8. Defendants transact business within the State of Iowa, contracted to sell and

supply their Bard Mesh products in the State of Iowa, and committed tortious acts and omissions in Iowa. Defendants' tortious acts and omissions caused injury to Plaintiff in the State of Iowa. Defendants employ sales representatives in the State of Iowa to sell their Bard Mesh products throughout the State, including the Bard Mesh implanted in Plaintiff. Defendants have purposefully engaged in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, medical devices including Bard Mesh in Iowa, for which they derived significant and regular income. The Defendants intended and reasonably expected that their defective mesh products, including Bard Mesh, would be sold and implanted in Iowa and could cause injury in Iowa.

9. Davol is registered to transact business in Iowa.

10. Venue is proper in the Southern District of Iowa pursuant to 28 U.S.C. 1391 because the events or omissions giving rise to Plaintiffs' claims occurred in this District.

11. Defendants have and continue to conduct substantial business in the State of Iowa and in this District, distribute Bard Mesh in this District, receive substantial compensation and profits from sales of Bard Mesh in this District, and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

FACTS COMMON TO ALL COUNTS

12. On or about February 13, 2007, Plaintiff Betty Sackett underwent hernia repair by Dr. Praveen Prasad at Mercy Medical Center in Des Moines, Iowa. A 15.5 x 20.5 cm CK Parastomal Bard Hernia patch, Cat. No. 0118004, Lot No. 43fqd384 was implanted in Plaintiff during this repair.

13. Defendants manufactured, sold, and/or distributed the Bard Mesh to Plaintiff, through her doctors, to be used for treatment of hernia repair.

14. On or about January 25, 2018, Plaintiff Betty Sackett underwent removal of the failed Bard Mesh by Dr. Praveen Prasad at Iowa Lutheran Hospital in Des Moines, Iowa.

15. Plaintiff continues to experience complications related to Bard Mesh.

16. Bard was, at all times relevant hereto, responsible for the actions of Davol and exercised control over Davol's functions specific to oversight and compliance with applicable safety standards relating to and including Bard Mesh sold in the United States. In such capacity, they committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards related to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Their misfeasance and malfeasance caused Plaintiff to suffer injury and damages.

17. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of Bard Mesh, including providing the warnings and instructions concerning the product.

18. Among the intended purposes for which Defendants designed, manufactured and sold Bard Mesh was use by surgeons for hernia repair surgeries, the purpose for which the Bard Mesh was implanted in Plaintiff.

19. Defendants represented to Plaintiff and Plaintiff's physicians that Bard Mesh was a safe and effective product for hernia repair.

THE FDA'S 510(k) CLEARANCE PROCESS

20. The 510(k) clearance process refers to Section 510 (k) of the Medical Device Amendments of 1976 MDA of the Federal Food, Drug and Cosmetic Act. Under this process,

device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA had approved for sale before 1976, when the MDA was enacted.

21. No clinical testing is required under this process.

22. Subsequent amendments to the MDA allowed for 510(k) clearance of products deemed "substantially equivalent" to post-MDA, 510(k)-cleared devices.

23. Through this domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices approved for sale by the FDA before 1976 could be sold to patients in a matter of 90 days without any clinical testing.

24. Clearance for sale under the 501(k) process does not equate to FDA approval of the cleared device.

25. In 2012, at the request of the FDA, the National Institute of Health (NIH) conducted a thorough review of the 510(k) process, coming to the following major conclusion:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

26. The NIH explained, "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and effectiveness of individual medical devices . . . Thus it is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original

device classification program or through the 510(k) process."

27. Defendants cleared the Bard Mesh, and its related components, under the 510(k) Premarket Notification. Under Section 510(k) of the Federal Food, Drug and Cosmetic Act, a medical device does not have to go through the rigors of a clinical study to gain approval by the FDA. Instead, the device was supposed to demonstrate substantial equivalence to a predicate medical device.

28. On June 18, 2002, the Food and Drug Administration issued a document titled "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Guidance for Industry." The 26 page document starts by explaining:

> **FDA has determined that the resorbable adhesion barrier is a significant risk device as defined in 21 CFR 812.3(m)(4). The resorbable adhesion barrier is a class III device which is subject to premarket approval in accordance with section 515 of the Federal Food, Drug, and Cosmetics (FD&C) Act.**

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

29. Defendants are estopped from relying on any statutes of limitations or repose by virtue of their acts of fraudulent concealment, which include the Defendants' intentional concealment from Plaintiff and the general public that the Bard Mesh is defective, while continually marketing the Bard Mesh with the effects described herein.

30. Given the Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects – information over which the Defendants had exclusive control – and because Plaintiff could not reasonably have known the Hernia Mesh was defective, Defendants are estopped from relying on any statutes of limitations that might overwise be applicable to the claims asserted herein.

COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT

31. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

32. Defendants expected and intended the Bard Mesh product to reach users such as Plaintiff in the condition in which the product was sold.

33. The implantation of Bard Mesh in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

34. At the time the Bard Mesh was implanted in Plaintiff's body, the product was defectively manufactured.

35. Defendants' poor quality control and general non-compliance resulted in the non-conformance of the Bard Mesh implanted in Plaintiff. The Bard Mesh implanted in Plaintiff did not conform to the Defendants' intended manufacturing and design specifications.

36. Upon information and belief, Defendants utilized substandard and adulterated polypropylene and raw materials used to make the coating on their finished Bard Meshes, which deviated from Defendants' material and supply specifications.

37. As a direct and proximate result of the defective manufacture of the Bard Mesh, Plaintiff suffered injuries and damages as summarized herein.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

38. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

39. Defendants' Bard Mesh was defectively designed and/or manufactured, was

not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the Bard Mesh, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tumor formation, cancer, tissue damage and/or death; and other complications.

40. When affixed to the body's tissue, the impermeable coating of the Mesh prevents fluid escape, which leads to seroma formation, and which in turn can cause infection or abscess formation and other complications.

41. The coating provides an ideal bacterial breeding ground in which the bacteria cannot be eliminated by the body's immune response, which allows infection to proliferate.

42. Defendants utilize Ethylene Oxide ("ETO") in an attempt to sterilize the Mesh. ETO is an effective disinfectant; however, dry spores are highly resistant to ETO. Moisture must be present to eliminate spores using ETO. Presoaking the product to be sterilized is most desirable, but high levels of humidity during the ETO process can also be effective in eliminating spores. Mesh implanted with spores will eventually result in an infection. The spores can remain dormant for extended periods of time, resulting in infections months or years after implantation with the Mesh. The following non-exhaustive literature discusses the necessity of moisture during ETO sterilization.

> A. In January of 1989, a review on sterilization methods of medical devices was published in the Journal of Biomaterials Applications. ETO was among the sterilization methods reviewed. **ETO was noted to be highly resistant to dry spores, moisture must be**

> **present; presoaking most desirable. Experiments demonstrated the importance of the state of humidification of organisms at the time of their exposure to ETO. Desiccation of the spores prior to ETO exposure produces a small but significant percentage of organisms which are highly resistant to the sterilization process. Similar resistance to destruction by ETO occurs in desiccated staphylococcus aureus. Rehumidification of such organisms can require prolonged exposure to an atmosphere having a 50 to 90 percent relative humidity. Moisture has been found to be a critical factor in achieving sterility with gaseous ETO. No gas sterilizer can effectively kill desiccated spores.**
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> Dempsey, D.J. and Thirucote, R.R., *Sterilization of medical devices: A Review.* Journal of Biomaterials Applications, 3(3), pp. 454-523 (1988). DOI: 10.1177/088532828800300303

43. The Bard Mesh is acidic, causing bacteriostasis (inhibition of the growth of bacteria without killing the bacteria), which results in the inability to properly validate sterilization.

44. The coating on the Defendants' Bard Mesh is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

45. The coating is designed and intended to resorb in less than 30 days.

46. When the coating is disrupted, degrades, and/or resorbs, the "naked" polypropylene mesh and PGA is exposed to the adjoining tissue and viscera, and can become adhered to organs, and cause incarceration of organs, and fistula formation.

47. The Bard Mesh has a solid, flat, relatively smooth and continuous surface, which promotes tumor and cancer formation via the "Oppenheimer Effect", a phenomenon identified in the 1950s.

48. The solid, flat, relatively smooth and continuous surface of the Bard Mesh inhibits the body's ability to clear toxins.

49. These manufacturing and design defects associated with the Bard Mesh were directly and proximately related to the injuries suffered by Plaintiff.

50. Neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of Bard Mesh. Moreover, neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the risks associated with the Bard Mesh.

51. The Bard Mesh implanted in Plaintiff failed to reasonably perform as intended. The Bard Mesh caused serious injury and had to be surgically removed via invasive surgery, and necessitated additional invasive surgery to repair the hernia that the Bard Mesh was initially implanted to treat.

52. At the time the Bard Mesh was implanted in Plaintiff's body, the product was defectively designed. As described above, there was an unreasonable risk that the Bard Mesh would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

53. Defendants expected and intended the Bard Mesh product to reach users such as Plaintiff in the condition in which the product was sold.

54. The implantation of Bard Mesh in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

55. The risks of the Bard Mesh significantly outweigh any benefits that defendants contend could be associated with the product. The coating, which is not used in any other hernia mesh product sold in the United States, incites an intense inflammatory response, leading to

encapsulation, deformation, scarification and contraction, migration, erosion and rejection. The impermeable coating leads to seroma formation, and provides a breeding ground for infection, and protects bacteria from being eliminated by the body's natural immune response. This coating also caused immunogenic response, and was known to be cytotoxic.

56. The coating of the Bard Mesh, which was marketed, promoted and intended as a barrier against adhesion to the bowel, was only temporary; it was expected and intended to degrade over time inside the body. Thus, this coating prevented tissue ingrowth in the short term, and degraded in the long-term, eventually leaving the "naked" polypropylene mesh and PGA exposed to the internal viscera and tissues,. Once exposed to the viscera, the polypropylene and PGA will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the coating (to prevent adhesion to the bowel and internal viscera) was non-existent; the product provided no benefit while substantially increasing the risks to the patient.

57. The polypropylene mesh within the defective coating of the Mesh was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the Bard Mesh. The particular polypropylene material used in the Bard Mesh was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body, further exacerbating the adverse reactions to the product once the coating degraded. When implanted adjacent to the bowel and other internal organs, as Defendants intended for Bard Mesh, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

58. The appropriate treatment for complications associated with Bard Mesh involves

additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to the patient.

59. The Bard Mesh was designed and intended for intraperitoneal implantation, which required the product to be placed in contact with internal organs, which unnecessarily increased the risks of adhesion, erosion, fistula formation and other injuries.

60. At the time the Bard Mesh was implanted in Plaintiff, there were safer feasible alternative designs for hernia mush products, including but not limited to, a flat, non-coated, single-layer mesh placed away from the bowel.

61. The Bard Mesh product cost significantly more than competitive products because of its unique coating, even though the coating provided no benefit to consumers, and increased risks to patients implanted with these devices.

62. The Bard Mesh has a solid, flat, relatively smooth and continuous surface. Medical devices which utilize this design greatly increase the risk of tumor and cancer formation:

A. In 1958, a study supported by a research grant from the National Cancer Institute titled The Latent Period in Carcinogenesis by Plastics in Rats and its Relation to the Presarcomatous Stage was published in the Journal of Cancer. **The presence of polymer in a sheet form appears to be of primary importance, as shown by the manifold increase in the percentage of tumors induced by this form, as opposed to textiles, sponges, powders, etc. This may act in some way as a block to the free interchange of tissue constituents, subjecting some cells to an altered environment and changing their pattern of growth. Whether the primary cause is lack of nutrients or oxygen, or the accumulation of products of metabolism, or even a freeing of the cell from some hormonal control, is not at present clear, but undoubtedly the cell is placed under conditions that are favorable to autonomous, unregulated growth. Plastics embedded subcutaneously in rodents in film or sheet form induce malignant tumors in significant numbers (up to 50%), but embedded in other forms, such as textiles, sponges, or powders, they induce tumors only**

rarely.

Oppenheimer, B.S. et al, *The Latent Period in Carcinogenesis by Plastics in Rats and its Relations to the Presarcomatous Stage.* Journal of Cancer 1(11). 204-213 (1958).

63. The Bard Mesh implanted in Plaintiff failed to reasonably perform as intended, and had to be surgically removed necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus provided no benefit to her.

64. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff suffered injuries and damages as summarized herein.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

65. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

66. At the time the Bard Mesh was implanted in Plaintiff's body, the warnings and instructions provided by Defendant for the Bard Mesh were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

67. Defendants expected and intended the Bard Mesh product to reach users such as Plaintiff in the condition in which the product was sold.

68. Plaintiff and Plaintiff's physicians were unaware of the defects and dangers of Bard Mesh, and were unaware of the frequency, severity and duration of the risks associated with the Bard Mesh.

69. The Defendants' Instructions for Use provided with Bard Mesh expressly

understates and misstates the risks known to be associated specifically with the Bard Mesh by representing that the complications such as inflammation associated with the Bard Mesh are "possible complications." The Bard Mesh will always incite severe inflammation once implanted. The inflammation caused by the Bard Mesh is chronic in nature and systemic, not acute localized inflammation. No other surgical mesh sold in the United States has the dangerous and defective coating, which itself causes or increases the risks of numerous complications, including increased risk of seroma formation, immunologic response, increased risk for infection, and increased inflammatory reaction and foreign body response. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Mesh.

70. The Defendants' Instructions for Use for the Mesh failed to adequately warn Plaintiff's physicians of numerous risks which Defendants knew or should have known were associated with the Mesh, including the risks of the product's immunologic response, pain, dehiscence, encapsulation, rejection, migration, scarification, contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, bowel obstruction, or hernia incarceration or strangulation.

71. Defendants failed to adequately train or warn Plaintiff or Plaintiff's physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.

72. Defendants failed to adequately warn Plaintiff or Plaintiff's physicians that the surgical removal of the Bard Mesh in the event of complications would leave the hernia unrepaired, the resulting hernia would be much larger than the original, and would necessitate further, more complicated medical treatment to attempt to repair the same hernia that the failed

Mesh was intended to treat.

73. Defendants represented to physicians, including Plaintiff's physician, that the coating would prevent or reduce adhesions, and expressly intended for the Mesh to be implanted in contact with the bowel and internal organs and marketed and promoted the product for said purpose. Defendants failed to warn physicians that the coating was only temporary and therefore at best would provide only a temporary adhesion barrier, and when the coating inevitably degraded, the exposed polypropylene and PGA would become adhered to the bowel or tissue.

74. Defendants failed to warn Plaintiff and Plaintiff's physicians that the Bard Mesh was considered a significant risk by the FDA.

75. Defendants marketed and continue to market the Bard Mesh in brochures and online without disclosing or making evident that PGA is utilized in the Bard Mesh.

76. With respect to the complications that were listed in Defendants' warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with Bard Mesh were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.

77. If Plaintiff and/or Plaintiff's physicians had been properly warned of the defects and dangers of Bard Mesh, and of the frequency, severity and duration of the risks associated with the Bard Mesh, Plaintiff would not have consented to allow the Bard Mesh to be implanted, and Plaintiff's physicians would not have implanted the Bard Mesh in Plaintiff.

78. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized herein.

COUNT IV: NEGLIGENCE

79. Plaintiff incorporates herein by reference the allegations in all prior Paragraphs as if fully set forth herein.

80. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for Bard Mesh, but failed to do so.

81. Defendants knew, or in the exercise of reasonable care should have known, that Bard Mesh was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom Bard Mesh was implanted. Defendants knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in the Bard Mesh.

82. Defendants knew or should have known that the MSDS for the polypropylene used to manufacture its Mesh prohibited permanently implanting the polypropylene into the human body.

83. Defendants utilized non-medical grade polypropylene.

84. Defendants knew or should have known that polypropylene is not inert and would degrade, flake, chip, and disperse throughout the body once implanted.

85. Defendants knew or should have known that polypropylene incites a severe inflammatory response once implanted and continues to incite a severe inflammatory response indefinitely or until removed.

86. Defendants knew or should have known that every piece of polypropylene that flakes off and migrates throughout the body also incites its own chronic inflammatory response wherever it embeds.

87. Defendants knew or should have known that PGA induces an intense local inflammatory response following implantation.

88. Defendants knew or should have known that carboxymethylcellulose induces an intense local inflammatory response following implantation.

89. Defendants knew or should have known of the cytotoxic and immunogenic properties of the coating on the Mesh prior to introducing it into the stream of commerce.

90. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for Bard Mesh, Plaintiff suffered injuries and damages as summarized herein.

COUNT V: BREACH OF EXPRESS WARRANTY

91. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

92. At all relevant and material times, Defendants manufactured, marketed, sold, and distributed and otherwise placed in to the stream of commerce Bard Mesh.

93. In advertising, marketing and otherwise promoting Bard Mesh to physicians, hospitals and other healthcare providers, Defendants expressly warranted that their Bard Mesh was safe for use and reasonably fit for their intended purposes. In advertising, marketing and otherwise promoting Bard Mesh, Defendants intended that physicians, hospitals and other healthcare providers rely upon their representations regarding safety and fitness in an effort to induce them to implant Bard mesh in their patients.

94. With respect to the Plaintiff, Defendants intended that Bard Mesh be implanted by Plaintiff's treating surgeon in a reasonable and foreseeable manner in which it was implanted and

in accordance with the instructions for use and product specifications provided by Defendants. The Plaintiff was in privity with Defendants.

95. Defendants expressly warranted to physicians, hospitals, and other healthcare providers and the general public including Plaintiffs that Bard Mesh was safe and fit for use by consumers, that it was of merchantable quality, that its risks, side effects and potential complications were minimal and comparable to other hernia mesh products, that it was adequately researched and tested, and that it was fit for intended use. Plaintiff and Plaintiff's physicians and healthcare providers reasonably relied upon Defendants' express representations and warranties, and consequently, Plaintiff was implanted with Defendants' Bard Mesh.

96. The Bard Mesh was manufactured from polypropylene, polyglycolic acid fibers coated with a bioresorbable, chemically modified sodium hyaluronate, carboxymethylcellulose, and polyethylene glycol based hydrogel. The coating was represented by the Defendants to prevent or minimize adhesion and inflammation and to facilitate incorporation of the mesh into the body, but it did not. Instead, the coating caused an intense systemic inflammatory and chronic foreign body response, resulting in an adverse tissue reaction including damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper or delayed healing.

97. Defendant breached these express warranties because the Bard Mesh implanted in Plaintiff was unreasonably dangerous, defective, and not as Defendants had represented.

98. Defendants breached express representations and warranties made to the Plaintiff, as well as Plaintiff's physicians and healthcare providers, with respect to the Bard Mesh, including, but not limited to, the following particulars:

A. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare

providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' Bard Mesh was safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Bard Mesh;

B. Defendants represented to Plaintiff and their physicians and healthcare providers that the Defendants' Bard Mesh was safe and/or safer than other alternative procedures and devices on the market, meanwhile Defendants fraudulently concealed information that demonstrated that Bard Mesh was not safer than alternative therapies and products available on the market; and

C. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers that the Defendants' Bard Mesh was more efficacious than other alternative procedures, therapies and/or devices, meanwhile Defendants fraudulently concealed information regarding the true efficacy of Bard Mesh.

99. Defendants' breach of their express warranties resulted in the implantation of an Unreasonably dangerous and defective product into the Plaintiff, placing Plaintiff's health and safety in jeopardy.

100. At the time of making such express warranties, Defendants knew or should have known that Defendants' Bard Mesh does not conform to the express warranties and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety so as to warrant the imposition of punitive damages.

COUNT VI: VIOLATION OF CONSUMER PROTECTION LAWS

101. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

102. Plaintiff purchased and used the Defendants' Bard Mesh primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

103. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Defendants' Bard Mesh, and would not have incurred related medical cost and injury.

104. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Bard Mesh that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

105. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

A) Representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have;

B) Advertising goods or services with the intent not to sell them as advertised; and

C) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

106. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' Bard Meshes. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' Bard Meshes.

107. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' Bard Meshes.

108. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Bard Mesh, and would not have incurred related medical cost.

109. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

110. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

111. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations.

- 15 U.S.C. §§ 2301-2312 (1982)
- N.J. Stat. Ann §§ 56:8-1, *et seq.*
- R.I. Gen. Laws §§ 6-13.1, *et seq.*

112. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

113. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices

and false advertising, by knowingly and falsely representing that the Defendants' Bard Meshes were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

114. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

115. Defendants had actual knowledge of the defective and dangerous condition of the Defendants' Bard Mesh and failed to take any action to cure such defective and dangerous conditions.

116. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

117. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

118. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

119. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

COUNT VII: GROSS NEGLIGENCE

120. Plaintiff incorporates herein by reference the allegations in all prior paragraphs

as if fully set forth herein.

121. The wrongs done by defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards, was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

122. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

123. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

124. Plaintiff also alleges that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

COUNT VII: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

125. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

126. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' Bard Mesh to Plaintiff.

127. Defendants carelessly and negligently concealed the harmful effects of the Defendants' Bard Mesh from Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

128. Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the Bard Mesh to Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

129. Plaintiff was directly impacted by Defendants' carelessness and negligence, in that Plaintiff has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the Bard Mesh sold and distributed by Defendants.

130. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the Bard Mesh to Plaintiff individually and/or Plaintiff's physician after Plaintiff sustained emotional distress, severe physical injuries, and economic loss.

131. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the Bard Mesh to Plaintiff individually and/or Plaintiff's physician knowing that doing so would cause the Plaintiff to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

132. As a proximate result of the Defendants' conduct, Plaintiff has been injured, sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

COUNT IX: FRAUDULENT CONCEALMENT

133. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

134. At all times relevant hereto, it was known or knowable to Defendants that their Products caused large numbers of complications. Moreover, it was known or knowable to Defendants that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices. If was known or knowable to Defendants that the safety and efficacy of its Products had not been proven with respect to, among other things, the product, its components, its performance, and its method of insertion. It was known or knowable to Defendants that the Products were not safe and effective. Defendants continued to represent that its Products were safe and effective.

135. Despite what was known or knowable to Defendants about the lack of safety and efficacy of its Products, Defendants failed to disclose this information to the Plaintiff, to Plaintiff's physicians, and to the public at large.

136. At all times relevant hereto, Defendants had the duty and obligation to disclose to Plaintiff and Plaintiff's physicians the true facts concerning the Products, that is, that said Products were dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and how likely it was to cause serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts prior to the time that Plaintiffs were implanted with Defendants' Products.

137. Defendants were under a duty to Plaintiffs to disclose and warn of the defective nature of the Products because:

A. Defendants were in a superior position to know the true quality, safety, and efficacy of its Products;

B. Defendants knowingly made false claims about the safety and quality of its Bard Mesh documents and marketing materials; and

C. Defendants fraudulently and affirmatively concealed the defective nature of the Bard Mesh from the Plaintiff.

138. The facts concealed and/or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendants' Products.

139. At all times relevant hereto, Defendants and each of them, willfully, intentionally, and maliciously concealed facts as set forth above from Plaintiffs and their physicians with the intent to defraud, as alleged herein.

140. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Products so that Plaintiffs would request and purchase the Defendants' Products, and their healthcare providers would dispense, prescribe, and recommend the Defendants' Products, and Plaintiffs justifiably acted or relied upon the concealed and/or non-disclosed facts to their detriment.

141. At all times relevant hereto, neither Plaintiffs nor their physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not have reasonably relied upon said representations of safety and efficacy and utilized Defendants' Products in their treatment. Defendants' failure to disclose this

information was a substantial factor in Plaintiff's physicians selecting Defendants' Products. The failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff, as a patient.

142. As a direct and proximate result us this conduct, Plaintiff was injured.

COUNT X: NEGLIGENT MISREPRESENTATION

143. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

144. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that its Bard Mesh had not been adequately tested and found to be a safe and effective treatment. The representations made by Defendants were, in fact, false.

145. Defendants failed to exercise ordinary care in the representations concerning the Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Bard Mesh's high risk of unreasonable and dangerous side effects.

146. Defendants breached their duty in representing that the Defendants' Bard Meshes have no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical community.

147. As a foreseeable, direct, and proximate result of the negligent misrepresentation of Defendants, as set forth herein, Defendants knew, and had reason to know, that the Bard Mesh had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that they created a high risk – and/or higher than acceptable risk, and/or higher than reported and represented risk – of adverse side

effects, including, but not limited to, pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

148. As a direct and proximate result of the Defendants' conduct, Plaintiff has been injured and has sustained severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and economic.

PUNITIVE DAMAGES

149. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

150. Defendants failed to adequately test and study the Bard Mesh to determine and ensure that the product was safe and effective prior to releasing the product for sale for permanent human implantation, and Defendants continued to manufacture and sell Bard Mesh after obtaining knowledge and information that the product was defective and unreasonably unsafe.

151. Even though Defendants have other hernia repair mesh devices that do not present the same risks as the Bard Mesh, Defendants developed, designed and sold Bard Mesh, and continue to do so, because the Bard Mesh has a significantly higher profit margin than other hernia repair products. Defendants were aware of the probable consequences of implantation of the dangerous and defective Bard Mesh, including the risk of failure and serious injury, such as suffered by Plaintiff.

152. At all times relevant hereto, Defendants knew or should have known that Bard Mesh was inherently more dangerous with respect to the risk of foreign body response, allergic reactions, rejection, infection, failure, erosion, pain and suffering, organ perforation,

dense adhesions, tumor or cancer formation, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as the other severe and personal injuries which are permanent and lasting in nature.

153. Defendant's misrepresentation included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the Bard Mesh, which deprived Plaintiff and Plaintiff's implanting physicians of vitally necessary information with which to make a fully informed decision about whether to use Bard Mesh.

154. At all times material hereto, Defendants knew and recklessly and/or intentionally disregarded the fact that the Defendants' Bard Mesh can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatment.

155. At all times material hereto, Defendants knew and recklessly and/or intentionally disregarded the fact that Bard Mesh can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise the medical community and the general public, including Plaintiffs, of the same.

156. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries and the rate of complications associated with Bard Mesh.

157. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true and defective nature of Bard Mesh with its increased risk of side effects and serious complications, Defendants continue to aggressively market the Bard

Mesh to the medical community and to consumers without disclosing the true risk of such complications.

158. At the time that the Plaintiff was implanted with the Bard Mesh and since that time, Defendants knew that Bard Mesh was defective and unreasonably dangerous but continued to manufacture, produce, assemble, market, distribute, and sell Bard Mesh so as to maximize sales and profits at the expense of the health and safety of the public in a conscious, reckless and/or intentional disregard of the likely and foreseeable harm caused by Bard Mesh to members of the public including Plaintiff.

159. At all times material, Defendants have concealed and/or failed to disclose to the public the serious risks and the potential complications associated with Hernia Mesh in order to ensure continued and increased sales and profits, to the detriment of the public, including Plaintiff.

160. Defendants' conduct, acts and omissions, as described herein, are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable statutory and common law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

SPOUSAL LOSS OF CONSORTIUM

Plaintiff Richard Sackett, on his own behalf states:

161. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

162. At all times material, Richard Sackett was the husband of Betty Sackett.

163. As a direct result of the injuries suffered by Betty Sackett, which were proximately caused by the negligence of the Defendants, Plaintiff Richard Sackett has been deprived of the companionship, aid, services, affection and society of his wife, Betty Sackett.

PRAYER FOR RELIEF

Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally and pray for the following relief in accordance with applicable law and equity:

i. Compensatory damages to Plaintiffs for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, and loss of spousal consortium, together with interest and costs as provided by law;

ii. Restitution and disgorgement of profits;

iii. Punitive damages;

iv. Reasonable attorneys' fees as provided by law;

v. Past and future cost of all proceedings;

vi. All ascertainable economic damages;

vii. Prejudgment interest on all damages as allowed by law; and

viii. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all issues so triable.

Respectfully Submitted,
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Attorneys for Plaintiff

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